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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,488	11/13/2006	Shigehisa Wada	0599-0213PUS1	7587

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EXAMINER	
HURST, JONATHAN M	
ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
02/01/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/570,488	WADA ET AL.	
	Examiner	Art Unit	
	JONATHAN M. HURST	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/2009 has been entered.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 22-23 and 28-29 is rejected under 35 U.S.C. 102(b) as being anticipated by Demmer et al. (US 6,001,974)

In rejecting the claims, the examiner is basing the rejection of the selection of steps (2) and (3).

Regarding claims 22-23 and 28 Demmer et al. discloses a method of preparing a product solution by removing of biological components from a human derived biological components-containing solution which comprises subjecting the biological components-

containing solution to at least two of the following three treatment steps in succession; (See Abstract)

wherein the two treatment steps are (2) subjecting a solution to a step of removing a portion or all of proteins having a molecular weight equal to or higher than that of albumin by fractionation with a molecular sieve and retaining a portion of the solution from which the proteins have been removed; (See Col. 2 Line 36- Col. 3 Line 20 and Fig. 1 where treatment step 2 is performed in module 1)

and (3) subjecting a solution to a step of concentrating proteins by passing a the solution through a porous separation membrane and retaining the treated portion of the solution that does not pass through the porous membrane wherein the product solution is the retained, treated portion of the solution from at least two of the three treatment steps. (See Col. 2 Line 36- Col. 3 Line 20 and Fig. 1 where treatment step 3 is performed in module 1)

Regarding claim 29 Demmer et al. discloses an apparatus for preparing a solution by removing biological components having from a biological components-containing solution, wherein the apparatus comprises at least two modules joined by a flow path and selected from the following modules (2) a module for removing a portion or all of proteins having a molecular weight equal to or higher than that of albumin by fractionation with a molecular sieve; and (3) a module for concentrating proteins by

passing a portion of the solution through a porous separation membrane and retaining the portion of the solution that does not pass through the porous membrane. (See Abstract, Fig. 1 and Col. 2 Line 37- Col. 3 Line 35 where a module 1 contains membranes which remove at least a portion of protein of larger molecular weight than albumin and a second membrane module where some forms of protein are concentrated and retained).

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 24-26, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Demmer et al. (US 6,001,974) in view of Kim et al. (US 7,441,666).

In rejecting the claims, the examiner is basing the rejection of the selection of steps (2) and (3).

Regarding claims 24-26, are Demmer et al. discloses all the claim limitations as set forth above and does not appear to disclose a molecular sieve and or separation membrane being formed from one or more substances selected from cellulose, cellulose acetate, a polycarbonate, a polysulfone, a poly(methacrylic acid) ester, a

poly(acrylic acid) ester, a polyamide, polyvinylidene fluoride, polyacrylonitrile, polyethylene, and polypropylene.

Kim et al. discloses a method of preparing a product solution by removing of biological components from a human derived biological components-containing solution which comprises subjecting the biological components-containing solution to at least two of the following three treatment steps;

wherein the two treatment steps are (2) subjecting a solution to a step of removing a portion or all of proteins having a molecular weight equal to or higher than that of albumin by fractionation with a molecular sieve and retaining a portion of the solution from which the proteins have been removed; and (3) subjecting a solution to a step of concentrating proteins by passing a the solution through a porous separation membrane and retaining the treated portion of the solution that does not pass through the porous membrane wherein the product solution is the retained, treated portion of the solution from at least two of the three treatment steps. (See Abstract and Col. 23 Lines 23-55 where a solution containing proteins is passed through a membrane module and during which at least a portion of proteins having a molecular weight greater than or equal to albumin are removed from the solution and also during separation at least some forms or weights of proteins are concentrated and retained by the membrane while other proteins which pass through the membrane are also concentrated and retained in some form.)

The treatment steps (2) and (3) are conducted using a porous separation membrane containing one or more substances selected from cellulose and a polyamide. (See Col. 6 Lines 55-65 and Col. 23 Lines 25-55 where a membrane comprising polyamide is used to perform steps 2), and (3)).

Kim et al. further discloses the method further comprising a step wherein one or more substances selected from a group consisting of a polyethylene imine, an aminomethylpyridine, a polyphenol, a blue dye, a divalent metal ion, and an alkyl group-containing compound is fixed to the surface of the molecular sieve used in step (2). (See Col. 10 Lines 48-50 where a membrane to be used comprises a polymer and Col. 13 Lines 30-45 where polymer contains polyethylene imine and as such some will be fixed to the surface)

It would have been obvious to one of ordinary skill in the art at the time of invention to use a molecular sieve and/or separation membrane as disclosed by Kim et al. in the method of Demmer et al. because it is well known in the art to use sieves/membranes formed from the specific materials as described by Kim et al. to separate biological components from one another, including albumin, as is required by Demmer.

Regarding claim 30 Demmer et al. discloses all the claim limitations as set forth above as well as the apparatus for preparing a solution further comprising a liquid flow-out path to-be for transporting the prepared solution (See Fig. 1 where pure albumin C' flows out from module 3 and is characterized). Demmer further discloses characterizing the protein solution which comes out of a flow-out-path of the apparatus using a number of techniques (See Col. 3 Lines 21-35) but Demmer does not specifically disclose the liquid flow-out path joined to a liquid chromatograph, an electrophoretic apparatus, or a mass spectrometer.

Kim discloses in column 21, lines 25-50 that one way to characterizing proteins is by passing through a chromatograph.

It is noted that it is very well known in the art, as shown by Kim, to analyze and characterize protein containing solutions using liquid chromatographs, electrophoretic apparatuses, or a mass spectrometers in order to understand the constituents and or determine purity of a said solution as described by Demmer and connecting the output of one device to the input of another device when a product is meant to be conveyed from said one to another is very well known in the art. Therefor it would have been obvious to one of ordinary skill in the art at the time of invention to connect the liquid flow-out path of Demmer to a liquid chromatograph, an electrophoretic apparatus, or a mass spectrometer in order to quickly and efficiently convey the product for analysis as is well known in the art and required by Demmer. In addition, the substitution of one known technique for another is clearly within the scope of the skilled artisan.

Furthermore directly connecting the output of a filtration device to the inlet of a chromatograph is considered merely forgoing the use of separate modules where the two modules are known in the art to be used together. It has been held that one of ordinary skill in the art at the time the invention was made would have been led by the applied references to forgo use of separate modules, along with their function and benefit, where doing so is technically feasible and would reduce cost. See In re Thompson, 545 F.2d 1290, 1229, 188 USPQ 365, 367 (CCPA 1976).

6. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Demmer et al. (US 6,001,974) as applied above, and further in view of Comper (US 2002/0022236).

Regarding claim 27 Demmer et al. discloses all the claim limitations as set forth above as well as the method of preparing a solution according to the claim 22 does not specifically disclose the use of a blue dye added to the solution.

Comper discloses the use of a blue dye in order to detect albumin in a solution during a filtration process. (See [0085])

It would have been obvious to one of ordinary skill in the art at the time of the invention to add a blue dye as described by Comper to the solution of Demmer et al. because the dye of Comper because the blue dye is able bind to albumin selectively

over other unwanted compounds during detection (See Comper [0085]) and allows one to detect the amount, i.e. purity, of an albumin containing solution during a filtration process as is required by Demmer(See Demmer Col. 3 Lines 20-40).

While the reference does not explicitly disclose adding the blue dye before step (2) it is noted that selection of any order of performing disclosed process steps is prima facie obvious in the absence of new or unexpected results. See Ex parte Rubin , 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render prima facie obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to dye the albumin containing solution before step (2), as it amounts merely to change of the order of performing disclosed process steps in the absence of new or unexpected results.

Response to Arguments

7. Applicant's arguments with respect to claims 22-30 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues on pages 5-6 of the response that Kim et al. does not disclose two treatment steps performed subsequent to one another.

It is noted that while Kim et al. may not disclose performing two or more subsequent treatment steps as disclosed by claim 22 a new rejection has been provided and as such said arguments are moot.

Demmer et al. discloses a method of separating biological components from a solution using at least two steps performed subsequent to one another in two separate modules. It is noted that while the Albumin of Demmer et al. may not be retained by module 2 some form of solution is ,i.e. B" In Fig. 1, and such a retained material can broadly be considered a product.

Applicant argues on pages 6-7 of the response that "Demmer '974 discloses an apparatus for the separation of albumin having an anion exchange membrane adsorber module 1 and a cation exchange membrane adsorber 2. That is, both the modules 1 and 2 are ion exchange membrane adsorber modules. Both of these modules essentially correspond to module (1) of the apparatus of the presently claimed invention. Demmer '974 fails to disclose or suggest an apparatus which includes either a module that employs fractionation with a molecular sieve or a module that is used to

retain a portion of the treated solution which does not pass through a porous membrane, i.e. used to retain the "concentrate", as required by modules (2) and (3) in the apparatus of the present invention. Consequently, significant patentable distinctions exist over Demmer '974 such that the above rejections based on this reference must be withdrawn."

It is the examiner's position that Demmer et al. does disclose an apparatus and method for preparing a solution wherein two modules are present for preparing said solution. It is noted that while both modules of Demmer may in fact teach exchange membranes, which is a form of molecular sieve, and a module which is used to retain a portion of a solution. It is noted that while module 2 of Demmer may not retain Albumin as applicants may contemplate such a limitations is not found in the claims and as such arguments relating to Albumin separation and retention are moot.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN M. HURST whose telephone number is (571)270-7065. The examiner can normally be reached on Mon. - Thurs. 6:30-5:00; Every Fri. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571)272-1374. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. H./

Examiner, Art Unit 1797

/Michael A Marcheschi/

Supervisory Patent Examiner, Art Unit 1797